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Pedometer step count targets during pulmonary rehabilitation in COPD: a randomized controlled trial

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Running head: Pedometer step count targets during PR in COPD

Impact of this research:

This trial contributes high-quality evidence against the routine use of pedometers and step targets during pulmonary rehabilitation (PR) to improve physical activity levels, or enhance the established benefits of PR on exercise capacity and health-related quality of life in COPD in the short to medium term. It also demonstrates that pedometers may limit the positive benefits of PR on some aspects of quality of life in the short term, reflecting the added burden of wearing a pedometer on a daily basis. Considering this trial with other literature, current available evidence suggests that pedometers confer the most benefit to people with COPD when used outside of PR.

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At a glance:

Scientific knowledge on the subject: Despite the strong evidence base for pulmonary rehabilitation (PR) in improving exercise capacity in people with COPD, the effect on physical activity levels is uncertain. To date, three small, randomized controlled trials have examined the effect of pedometers on patients with COPD undergoing PR, with conflicting results (1-3). Methodologies and intervention strategies were varied, and studies underpowered, with high risk of effect size error and sample bias.

What this study adds to the field: This trial contributes high-quality evidence demonstrating that the routine use of pedometer feedback and step targets does not augment the effects of PR on physical activity levels, exercise capacity or health-related quality of life in patients with COPD. Pedometers might limit the effect of PR on some aspects of quality of life in the short term, reflecting the added burden of using the pedometer on a daily basis.

This article has an online data supplement, which is accessible from this issue's table of content online at www.atsjournals.org

ABSTRACT

Rationale: Increasing physical activity is a key therapeutic aim in COPD. Pulmonary rehabilitation (PR) improves exercise capacity, but there is conflicting evidence regarding its ability to improve physical activity levels.

Objective: To determine whether using pedometers as an adjunct to PR can enhance time spent in at least moderate intensity physical activity (time ≥ 3METs) in people with COPD.

Methods: In this single-blinded randomized controlled trial, participants were assigned 1:1 to receive control (PR comprising 8 weeks, two supervised sessions/week) or intervention (PR plus pedometer-directed step targets, reviewed weekly for 8 weeks). The randomisation process used minimisation to balance groups for age, sex, FEV_1 % predicted, and baseline exercise capacity and physical activity levels. Outcome assessors and PR therapists were blinded to group allocation. The primary analysis was by intention-to-treat and the trial registered with clinicaltrials.gov (Ref. NCT01719822).

Measurements: The primary outcome was change from baseline to 8 weeks in accelerometer-measured daily time ≥3METs.

Main results: 152 participants (72% male; mean (SD) FEV_1 % predicted 50.5 (21.2); median (Q1, Q3) time ≥3METS 46 (21, 92) minutes) were enrolled to intervention (n=76) or control (n=76). There was no significant difference in change in time ≥3METs between the intervention and control groups at 8 weeks (median (Q1, Q3) difference 0.5 (-1.0, 31.0) minutes; p=0.87) or at the 6 month follow-up (7.0 (-9, 27) minutes; p=0.16).

Conclusion: Pedometer-directed step count targets during an outpatient PR program did not enhance moderate intensity physical activity levels in people with COPD.

Word count: 245

Key words: physical activity, rehabilitation, COPD

INTRODUCTION

Increasing physical activity levels is a key therapeutic aim in chronic obstructive pulmonary disease (COPD) (4) because physical inactivity is associated with increased risk of mortality and exacerbations, greater decline in lung function, and impaired quality of life (5-7). There is strong evidence for the effectiveness of pulmonary rehabilitation (PR) on exercise capacity in COPD (8), but the effect of PR on physical activity levels is modest (9).

Pedometers may help people to become more active. A meta-analysis of 18 observational studies and 8 randomized controlled trials involving 2,767 outpatients found pedometer use was associated with a significant increase in physical activity levels (10). In a recent single-centre randomized controlled trial among stable COPD patients, a pedometer-based physical activity program led to significantly greater improvement in physical activity levels, exercise capacity and quality of life, when compared to simple encouragement to be more active (11). In contrast, Burtin and colleagues showed that the addition of simple physical activity counselling alone did not enhance the effects of PR on physical activity levels ((12).

We postulated that pedometers could enhance the effects of PR on physical activity levels. To date, three small, randomized controlled trials have explored the effect of pedometers as an adjunct to PR (1-3). The results were conflicting, reflecting intervention heterogeneity and trial methodologies. The trials were also underpowered (n=16 to 39), and at high risk of effect size error and sample bias (1-3).

The aim of this trial was to determine the short- and medium-term effectiveness of pedometer-directed step targets, as an adjunct to outpatient PR, on physical activity levels, exercise capacity and health-related quality of life in people with stable symptomatic COPD. We hypothesized that the use of pedometers would enhance the short- and medium- term effects of PR on physical activity levels, exercise capacity and health-related quality of life.

METHODS

Trial design and participants

We conducted a parallel, two-group, assessor-blinded, randomized controlled trial investigating the effect of a pedometer intervention during and following PR on physical activity levels in people with COPD. Recruitment took place within the Harefield Hospital PR Unit, UK, between July 2012 and June 2014, from patients undergoing an initial PR assessment. Eligible participants were ≥35 years of age with a physician diagnosis of COPD consistent with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) criteria (13), with MRC dyspnea scale ≥2, who consented to supervised PR. Exclusion criteria included contraindication to exercise (e.g. significant cardiovascular co-morbidities), or participants choosing a community PR site without access to specialist exercise equipment. All participants provided written informed consent. The trial protocol was pre-registered with clinicaltrials.gov (Ref. NCT01719822) and approved by the West London Research Ethics Committee (Ref. 11/LO/1021).

Randomization and blinding

Following baseline assessment, participants were randomly allocated (1:1) to receive usual care or usual care plus the pedometer intervention. The allocation sequence was computer-generated (Minim), accessed by a researcher independent of the recruitment process, PR program provision, trial intervention, and outcome assessment. Minimisation was used to balance groups for age (≤/> 65 years), sex (male/female), GOLD stage (I-II/III-IV), Incremental Shuttle Walk Test (ISWT) distance (</≥170m), oxygen use (yes/no), and, Physical Activity Level (PAL </≥1.4) (14). It was not possible to conceal group allocation from participants. Subsequent assessment visits were completed immediately after the PR program (8 weeks) and 6 months following the end of the PR program by assessors blinded to

group allocation. The statistician undertaking the primary statistical analysis (WB) was blinded to group allocation.

Intervention

Usual care was a standardized twice weekly supervised, 8-week outpatient PR program (see online supplement). The additional intervention was provision of a pedometer (Yamax Digiwalker CW700®, Yamax, Nottingham, UK), an individualised daily pedometer step count target (with weekly review for 8 weeks), and a step count diary provided during the PR program and the following 6 months. During PR, the daily pedometer step count target was an increase of 5% on the preceding week's average daily pedometer step count, with the first week's target derived from the baseline pre-PR assessment (e.g. 250 additional steps from a mean daily step count of 5,000). At this weekly step count review, each patient was counselled on the importance of achieving the pedometer step count and given advice on how to increase physical activity levels, focusing on barriers and opportunities arising during daily life. On completion of the PR program, participants in the intervention group received a final step count target based on a 20% increase in daily step count from the baseline pre-PR assessment and a step count diary. The detailed intervention protocol is described in the online supplement.

Outcomes

Participants wore an accelerometer (SenseWear®, Body Media Inc, Pittsburgh, USA) and pedometer for 7 days at the baseline, immediate post-PR, and 6 month follow-up assessment visits. Data recorded by the accelerometer included mean daily step count and time spent performing moderate intensity physical activity (time ≥3 METs) (7, 15, 16). The pedometer

measured daily step count and participants noted this number in the trial diary. Further information on the accelerometer and pedometer are in the online supplement.

Additional assessments included spirometry, functional exercise capacity using the ISWT (17) and health status with the Chronic Respiratory Questionnaire (CRQ). To gather feedback on pedometer usage, participants allocated to the intervention completed a telephone survey after the 6-month assessment; questions concerned positive and negative attributes of using the pedometer, physical activity undertaken after the study, and ideas that might motivate participants to exercise.

The primary outcome was change in daily time spent in at least moderate intensity physical activity (time ≥3 METs) from baseline to immediately following PR. Secondary outcomes were change in time ≥3 METs at 6 months following PR, and change in accelerometer and pedometer step counts, ISWT, CRQ domains and total score. Adverse events, hospitalizations and deaths were recorded throughout the trial.

Statistical analysis

Our sample size was based on a previous study, which demonstrated that a 3-month PR program increased the average daily walking time assessed using an accelerometer by a mean (SD) of 7 (35)% (18). We assumed an additional increase in moderate intensity physical activity of 20% would represent a clinically relevant improvement. To detect this using a two sample t-test with 80% power at the 0.05 significance level (two-sided), assuming equal variances, 50 participants per group were required. Based on PR studies of similar duration, we allowed for attrition during PR (22%) and from PR to 6 months post-PR (33%), and planned to recruit 155 participants overall.

Data were exported from a Microsoft® Office Access® 2010 database (Microsoft® Washington, USA) and analysis was completed by the trial statistician (WB) using Stata 14.1 (StataCorp LP, Texas, USA). The pre-specified primary analysis was by intention to treat. Missing data were explored and reported according to cause (19). Missing data were handled by a Markov Chain Monte Carlo method, using multiple imputations (10 datasets).. Data were assumed to be from a multivariate normal and data augmentation was applied to Bayesian inference with missing data. The data were log transformed for multiple imputation and then anti-logged.

Continuous data were expressed as mean with SD or 95% confidence intervals, and compared between groups with unpaired Student's t test (20). Non-normally distributed data were expressed as median (Q1, Q3) and compared between groups with Mann-Whitney U test (20). Categorical data were presented as percentages, and compared between groups with Pearson X^2 test (20). Outcomes were summarized as change from baseline. We used independent samples Student's t test (two-sided) or Mann Whitney U test to compare change in time ≥3 METs physical activity (primary outcome) and secondary outcomes immediately and 6 months following PR, by trial group (20). Sensitivity analysis considered complete-cases only, i.e. with paired observations, to account for possible impact of data imputation (online supplement: Table 1), and participants not achieving ≥150 minutes of moderate intensity physical activity each week at baseline (Table 3). A p-value <0.05 indicated statistical significance. Telephone survey data were handled using Microsoft® Office Excel® 2010 database (Microsoft®, Washington, USA) and content analysis was used to explore participants' experience of the intervention. We identified categories inductively from the interview data, with attention to terms and content.

RESULTS

Patient Flow

Figure 1 shows the CONSORT flowchart. In total, 155 people were consented with 152 randomized. Baseline characteristics are shown in Table 1. (21)

Outcomes were obtained for 122 (80.3%) and 113 (74.3%) participants at the immediate post-PR and 6-month follow-up assessments respectively, with similar attrition rates across groups (Figure 1). The planned intervention offered eight opportunities (each week of PR) for a new step count target to be set using 5% increments. In the intervention group, participants did not increase their target by 5% on a mean (SD) 5 (1) occasions during PR, because participants missed their PR session, could not be contacted by phone, or the previous weeks target was not met.

Valid accelerometer data for the primary outcome measure were available in 92 participants at the immediate post-PR assessment (intervention: n=46; control: n=46), and 93 participants at the 6-month follow-up assessment (intervention: n=44; control: n=49). The reasons for missing accelerometer data in the online supplement: Table 1. Missing data and dropouts were not associated with baseline age, sex, FEV_1 %predicted, exercise capacity, CRQ scores, or group allocation, and were considered missing at random. Consequently, multiple imputation was performed for the primary outcome, and analyzes involved all randomly assigned participants.

Primary Outcome

Table 2 and Figure 2 show change in time ≥3 METs from baseline to 8 weeks, and from baseline to 6 months following PR program. We found no significant between group difference in time ≥3 METs from baseline to 8 weeks (median (Q1, Q3) change: intervention

11 (-1, 33) minutes versus control 11 (-2, 28) minutes; p=0.62). Similarly, no significant between group difference in change in time ≥3 METs were observed at 6 months (intervention: 2 (-12, 25) minutes versus control: 12 (-7, 31) minutes; p=0.16) (Table 2 and Figure 2). This finding was consistent when only complete-cases were considered (online supplement 1: Table 2).

Secondary Outcomes

Figure 3 shows the overall progression in daily pedometer step count achieved during PR in the intervention group. The median (Q1, Q3) step count target for the final week of PR was 36 (0, 76)% higher than participants' baseline step count.

Consistent with the findings for the primary outcome measure, there were no significant between-group differences for accelerometer-recorded step count, pedometer-recorded step count, or ISWT at either time point (Table 2). At all time-points, the median accelerometer-recorded daily step count was greater than the pedometer-recorded step count, the discrepancy potentially arising from the poor accuracy of pedometers at slow walking speeds (21).

Unexpectedly, short-term improvements in CRQ scores following PR were significantly greater in the control group, as compared to the intervention group, for the fatigue ($p<0.01$) and mastery ($p=0.047$) domains as well as the total score ($p<0.01$). We also adjusted for baseline CRQ values and the group effect for differences in the fatigue domain and total score remained significant (online supplement: Table 3). However, between-group differences in CRQ did not persist at 6 months.

Given recent insights suggesting the effects of adjunct interventions during PR depend on them being offered in a targeted manner (22), we undertook a post-hoc sensitivity analysis

only considering the 38/152 (25%) participants with low baseline physical activity levels (≤150 minutes of moderate intensity physical activity each week), as per international guidelines (23, 24). The finding for the primary outcome did not change at 8 weeks (median (Q1, Q3) change 10 (2, 18) vs. 10 (6, 15) minutes, p=0.20) nor at the 6 month follow up (2 (-1, 25) vs. 14 (5, 31) minutes, p=0.52) (Table 3). There were no longer significant differences in CRQ scores following PR, suggesting the pedometer intervention blunts CRQ response to PR principally in those with higher levels of physical activity at trial entry (Table 3). Data for patients achieving ≥150minutes of moderate intensity physical activity per week is presented in the online supplement: Table 4.

The survey feedback on the pedometer was mixed. Some participants felt positive about the intervention, "it was interesting to get feedback…good to push myself" and that it provided "an incentive to go walking", whilst other reported issues with its use, e.g. "it needed to be clipped onto a waistband and so it was impossible to wear a dress" or "it didn't pick up all of my steps". Others revealed they could "alter it (the step count) by shaking it". Some participants reported that they stopped using the pedometer following PR due to a change in clinical condition, such as after an exacerbation "I had a really bad chest infection…as I couldn't leave the house, I didn't see the point in wearing it", or perception of its role "I stopped because I became obsessed with the step count target". On completion of PR, participants reported that physical activity levels tended to decline due to lack of incentive to exercise or becoming unwell with a chest infection.

The proportion of participants experiencing adverse events during and following PR was similar between groups. One participant experienced an allergic reaction to the nickel baseplate of the accelerometer during baseline assessments, and as a result, was not randomized. In total, there were 56 hospital admissions (intervention 23; control 33 ; p=0.50).

Thirty of these admissions were for COPD (intervention 14; control 16 ; p=0.29). Four deaths (two in each group) were recorded during the study period.

DISCUSSION

Contrary to our hypothesis, this single-blind randomized controlled trial demonstrated that pedometer-directed step count targets did not enhance the short- or medium-term effects of PR on moderate intensity physical activity levels, daily step-count, exercise capacity, or health-related quality of life in people with COPD. Indeed, there was evidence that the intervention was associated with a reduced improvement in some aspects of health-related quality of life with PR , though this difference did not persist at 6 months.

To our knowledge, two previous trials (1, 3) and a sub-study of a larger trial (2) have examined the use of pedometers as an adjunct to PR. Findings have been conflicting, which may reflect intervention heterogeneity and small sample sizes. Our study bears similarities to that described by Kawagoshi and colleagues (3). Pedometer feedback was the main intervention, whilst an accelerometer was used to objectively measure physical activity levels. There was limited physical activity counselling other than simple monthly verbal reinforcement to increase physical activity. Unlike our study, the authors were able to demonstrate a significant between-group difference in walking time in favour of the intervention group at 1 year (3). However, only 27 patients completed the study with no attempt to impute missing data, and the PR program was home-based, low intensity and minimally supervised. In the study by de Blok and colleagues the intervention consisted primarily of four individual exercise-counselling sessions, with pedometers used as motivational and feedback tools (1). This study was very underpowered (only 16 patients in total completed), and the randomization process was not well described. Although both

intervention and control groups showed a significant increase in daily step count, there were no statistically significant between group differences (1). In a larger trial, Altenburg and colleagues also studied the effects of a lifestyle physical activity counselling program in stable COPD outpatients (2). The intervention included pedometers used as motivational and feedback tools. In a subgroup analysis of patients undergoing PR, the authors demonstrated a short-term additive improvement in daily step count with the intervention, but this did not persist at 15 months (2). There were marked differences between their study and ours. First, the Altenburg study cohort was considerably younger (mean age 54 years versus 68 years) with more severe airways obstruction (mean FEV_1 43% versus 50%). Second, the PR sub-study population was considerably smaller with only 37 and 23 patients providing data at 3 months and 15 months respectively with no attempt to impute missing data. Third, the primary outcome in the Altenburg study was pedometer step count, which has significant limitations; our choice of multisensory accelerometer is considered a more accurate measure of physical activity. Finally, there were differences in baseline physical activity parameters between the control and intervention groups of the PR sub-study. This was not corrected for in the between group difference analysis.

Four randomized controlled trials and two uncontrolled interventional studies outside of PR, using pedometers and either a physical activity counselling program (2, 11, 25) or an internet-mediated pedometer-based program (26-28), have generally been positive by showing improvements in daily pedometer step count. A number of possibilities may account for the difference in physical activity outcomes between our study and these studies. Our study used an accelerometer to assess the impact of the intervention on physical activity, whereas the aforementioned studies employed pedometers. The capacity of pedometers to reliably measure physical activity is disputed owing to inconsistent construct and convergent validity and reliability at slow walking speeds, as well as the ability to manipulate the step count by

shaking the device (21, 29-32). Three of the studies (25, 27, 28) were small (range 24 to 35 participants) and only two studies provided a sample size calculation (2, 11). The contact time with healthcare professionals was greater in the aforementioned studies with time-periods ranging from 12 to 52 weeks (25, 26) in contrast to 8 weeks in our study. Furthermore, only one study in addition to ours assessed the medium-term impact of the intervention on physical activity levels (33).

There were a number of important secondary findings in this study. The use of a pedometer appeared to blunt the effects of PR on some health-related quality of life domains. This may reflect the added burden of using a pedometer and step count diary as evidenced by some negative feedback in the qualitative interviews. The reduction in pedometer step count from week 8 of PR program to post-PR assessment is noteworthy as it suggests that participants rapidly became more sedentary on stopping PR. This was further compounded by the consistent drop in physical activity levels from immediately to 6 months post-PR in both groups, which may indicate that an 8-week outpatient PR program is insufficient to elicit long-term behaviour change (34).

Strengths of our study include the use of randomization and an intention to treat analysis to limit risk of bias, and an adequate sample size to test our *a priori* hypothesis. Our study is the largest trial to explore the adjunct use of pedometers during PR. Outcome assessors and PR staff were blinded to group allocation, and, although due to the nature of the intervention it was not possible to do this with the trial participants, the primary outcome of objective, accelerometer-recorded physical activity parameters partly mitigates this source of bias (35). Importantly, this data was measured independently of the intervention device. Our assessment of outcomes immediately and 6 months following PR was rigorous, allowing us to examine both short- and medium- term effects of the intervention.

There are limitations to consider. Our a priori sample size calculation required 50 subjects in both the intervention and control groups to complete at the immediate post-PR time-point. There was unexpectedly high invalid or missing data from the accelerometer, and primary outcome measure data was available in only 46 pedometer and 46 control subjects, so the study may be underpowered. However, imputation of accelerometer data partly mitigated this. In addition, there was a wide variability in physical activity levels as measured using the accelerometer. A number of different methods analysing physical activity data exist. At the time of study planning, we pre-specified the then recommended method by Watz and colleagues(7), which involves analysing 5 days of data: 3 weekdays and 2 weekend days. However recent data from Demeyer and colleagues (36) recommend analysing 4 weekdays with ≥8hours data and considering daylight time to help reduce variability. With hindsight, a greater focus on the behavioural aspects may have produced more positive results in our trial but we note a recent trial from Burtin et al (12) which used a comprehensive physical activity behavioural program (eight individual activity counselling sessions without pedometer feedback) alongside PR as their intervention. Like our study, this failed to show an additional benefit on physical activity levels compared with PR alone. In the PR setting, de Blok and colleagues also failed to augment the benefits of PR with a combined approach of physical activity counselling with pedometer feedback (1). However, our intention was to design an intervention that was pragmatic and feasible to implement easily into a standard PR program without significant increase in staff time, and that would encourage patient self-management.

Conclusion

The study findings indicate that pedometer-directed step targets do not enhance the effects of PR on short- or medium-term physical activity levels, exercise capacity or health-related quality of life. These data do not support the routine use of pedometers to augment physical

activity during PR programs. In light of this, studies investigating alternative methods to enhance physical activity are necessary in order to realise the physical activity-associated health and economic benefits in people with COPD attending PR.

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FIGURE LEGENDS

FIGURE 1: CONSORT diagram.

FIGURE 2: Progression of daily pedometer step count targets during pulmonary rehabilitation among participants allocated to the pedometer intervention.

FIGURE 3: Daily time spent ≥3 METs before, after and 6 months following PR in the control and intervention groups.

TABLES

TABLE 1. Baseline characteristics

Variable	Whole group (n=152)	Intervention group (n= 76)	Control group (n=76)
Sex (male) (number (%))	110 (72)	56 (74)	54 (71)
Age (years)	68 (9)	69 (9)	68 (8)
FEV_1 (% predicted)	50.5 (21.2)	50.6 (20.7)	50.3 (21.8)
FEV_1/FVC	0.50 (0.15)	0.51 (0.15)	0.50 (0.16)
MRC score	3 (1)	3 (1)	3 (1)
Smoking status			
Never, number (%)	2 (1.3)	1 (1.3)	1 (1.3)
Former, number (%)	123 (80.9)	63 (82.9)	60 (79.0)
Current, number (%)	27 (17.8)	12 (15.8)	15 (19.7)
Pack-year history	40 (23, 60)	45 (34)	45 (29)
ADO Index	4.6 (1.6)	4.7 (1.6)	4.6 (1.6)
COTE Index	1 (0, 2)	1 (0, 3)	1 (0, 2)
$Sp0_2$ on room air	95 (3)	95 (3)	96 (3)
Current medication			
Long-acting bronchodilators	101 (66.4)	48 (63.2)	53 (69.7)
Short-acting bronchodilators	120 (78.9)	61 (80.3)	59 (77.6)
Inhaled corticosteroids	106 (69.7)	51 (67.1)	55 (72.4)
Oral steroids (maintenance)	13 (8.6)	7 (9.2)	6 (7.9)
Long-term oxygen therapy	4 (2.6)	1 (1.3)	3 (3.9)
Ambulatory oxygen therapy	16 (10.6)	8 (10.5)	8 (10.5)
Non-invasive ventilation	1 (0.7)	1 (1.3)	0 (0)
BMI, kg/m^2	28.1 (5.8)	28.7 (6.6)	27.6 (4.7)
Walking aid			
None, number (%)	136 (89.5)	69 (90.8)	67 (88.2)
Walking stick, number (%)	12 (7.9)	5 (6.6)	7 (9.2)
Walking frame, number (%)	4 (2.6)	2 (2.6)	2 (2.6)
4MGS, ms^{-1}	0.96 (0.24)	0.96 (0.21)	0.96 (0.26)
ISWT distance, meters	259 (145)	267 (156)	248 (138)
CRQ			
Dyspnea	13.4 (5.7)	14.1 (6.3)	12.7 (4.9)
Fatigue	13.9 (5.9)	14.6 (6.4)	13.1 (5.3)
Emotion	31.4 (9.4)	33.5 (9.5)	29.3 (8.8)
Mastery	18.2 (5.8)	19.2 (5.9)	17.1 (5.5)
Total	76.8 (22.8)	81.4 (23.9)	72.2 (20.9)
Accelerometer			
Moderate intensity physical activity (≥3 METs), min	46 (19, 85)	45 (20, 81)	47 (18, 103)
Daily accelerometer step count	3323 (1654, 5535)	3293 (1717, 5502)	3456 (1567, 5925)
Daily pedometer step count	2418 (1440, 4261)	2329 (1416, 4449)	2531 (1440, 4062)

Data are mean (SD) or median [Q1, Q3] unless stated otherwise. FEV_1: Forced Expiratory Volume in 1 second; FVC: Forced Vital Capacity; MRC: Medical Respiratory Council Dyspnea Scale; ADO Index: Age Disability Obstruction Index; COTE Index: COPD Specific Co-morbidity Index; 4MGS: 4 Meter Gait Speed; ISWT: Incremental Shuttle Walk Test; CRQ: Chronic Respiratory Questionnaire; METs: Metabolic Equivalents

TABLE 2. Change in primary and secondary outcome measures in intervention and control groups

	Change baseline to immediately following PR		p value	Change baseline to 6 months following PR		p value
	Intervention (n=63)	**Control (n=59)**		**Intervention (n=56)**	**Control (n=57)**	
Primary outcome: Time spent ≥3 METs (minutes/day)	11 (-1, 33)	11 (-2, 28)	0.62	2 (-12, 25)	12 (-7, 31)	0.16
Secondary outcomes: Accelerometer step count (steps/day)	272 (-342, 782)	155 (-438, 867)	0.99	-263 (-778, 197)	-461 (-1168, -62)	0.09
Pedometer step count (steps/day)	727 (-1493, 3119)	892 (-1187, 2534)	0.55	116 (-1698, 3200)	481 (-1931, 1781)	0.85
ISWT distance (meters)	60 (20, 90)	50 (10, 90)	0.83	30 (0, 70)	10 (-30, 70)	0.25
CRQ						
Dyspnea	3.7 (2.1 to 5.2)	5.6 (4.2 to 7.0)	0.07	1.8 (-0.1 to 3.6)	3.7 (2.1 to 5.3)	0.10
Fatigue	2.0 (0, 5.0)	4.0 (2.0, 6.0)	0.008	1.0 (-0.3 to 2.0)	2.0 (0.7 to 3.4)	0.19
Emotion	3.1 (1.9 to 4.4)	5.3 (3.3 to 7.3)	0.07	0.5 (-3.0, 4.0)	2.0 (-1.0, 6.0)	0.12
Mastery	1.8 (1.0 to 2.7)	3.4 (2.1 to 4.7)	0.047	0.5 (-1.0, -3.0)	2.0 (-2.0, 5.0)	0.29
Total	11 (3.0, 20.0)	20 (8.0, 27.0)	0.008	3.0 (-8.0, 16.0)	10 (-2.0, 19.0)	0.07

Data are mean (95%CI) or median (Q1, Q3). METs: Metabolic Equivalents; ISWT: Incremental Shuttle Walk Test; CRQ: Chronic Respiratory Questionnaire (*The CRQ domain scores range from: dyspnea: 5 to 35; fatigue: 4 to 28; emotion: 7 to 49; mastery: 4 to 28. The total score of the CRQ-SA ranges from 20 to 140 with higher scores representing better health status)*

TABLE 3. Baseline characteristics and change in primary and secondary outcome measures in the intervention and control groups restricted to participants not achieving ≥150 minutes of moderate intensity physical activity per week at baseline

Variable	Baseline (n=38)		-		
	Intervention (n=19)	Control (n=19)	-		
Sex (male) (number (%))	14 (74)	14 (74)	-		
Age (years)	70 (7)	69 (8)	-		
FEV_1 (% predicted)	49.1 (20.2)	47.1 (23.8)	-		
FEV_1/FVC	0.52 (0.16)	0.47 (0.18)	-		
MRC score	3 (1)	4 (1)	-		
BMI (kg/m^2)	32.6 (7.8)	29.1 (3.8)	-		
	Change baseline to immediately following PR (n=38)			Change baseline to 6 months following PR (n=38)	
	Intervention (n=19)	Control (n=19)	p value	Intervention (n=19)	Control (n=19)	p value
Primary outcome: Time ≥3 METs (minutes/day)	10 (2 to 18)	10 (6 to 15)	0.20	2 (-1, 25)	14 (5, 31)	0.52
Secondary outcomes: Accelerometer step count (steps/day)	229 (131 to 588)	206 (186 to 599)	0.60	1 (-436, 655)	-530 (-933, -292)	0.05
Pedometer step count (steps/day)	285 (-20, 779)	461 (35, 1170)	0.72	505 (-744, 1128)	258 (-243, 1236)	1.0
ISWT distance (meters)	32 (4 to 60)	46 (4 to 96)	0.59	10 (-25 to 45)	-3 (-53 to 59)	0.82
CRQ						
Dyspnea	3.8 (-0.3 to 7.2)	6.0 (2.8 to 9.0)	0.34	0.9 (-2.0 to 3.9)	4.2 (-0.8 to 7.5)	0.09
Fatigue	2.2 (-0.2 to 4.3)	3.6 (1.8 to 5.4)	0.31	1.3 (-1.6 to 4.2)	1.8 (-1.3 to 4.9)	0.57
Emotion	3.5 (-0.3 to 6.7)	3.4 (0.1 to 6.9)	0.96	-2.2 (-9.6 to 5.2)	1.6 (-2.8 to 6.0)	0.27
Mastery	2.6 (-0.5 to 4.6)	2.7 (0.1 to 5.3)	0.94	-1.1 (-6.4 to 4.2)	0.7 (-2.3 to 3.7)	0.50
Total	11.6 (3.6 to 19.5)	15.6 (6.7 to 24.5)	0.52	-1.1 (-16.6 to 14.5)	8.0 (-3.9 to 20.2)	0.23

Data are mean (SD), mean (95%CI) or median (Q1, Q3). METs: Metabolic Equivalents; ISWT: Incremental Shuttle Walk Test; CRQ: Chronic Respiratory Questionnaire

FIGURES

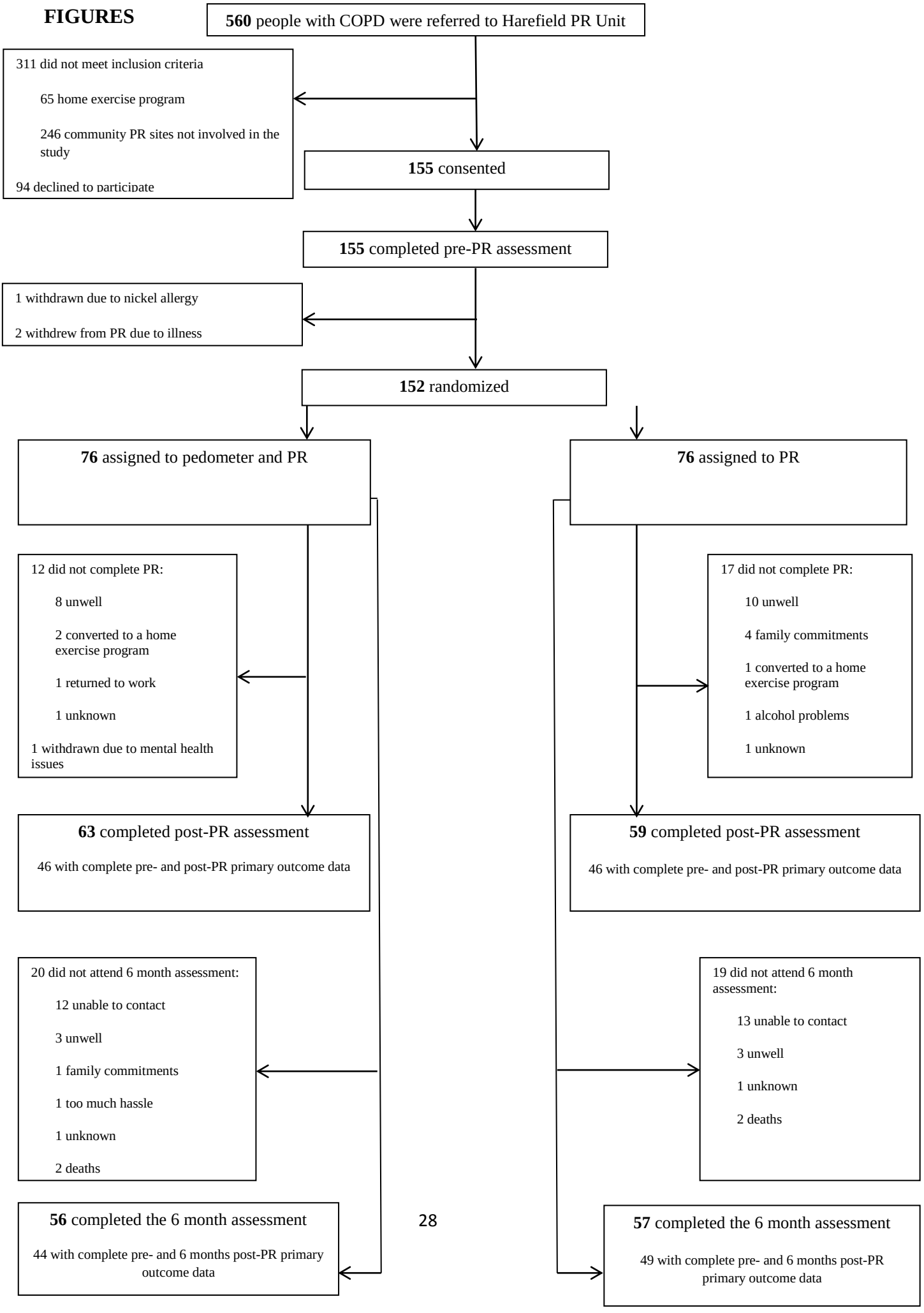
560 people with COPD were referred to Harefield PR Unit
311 did not meet inclusion criteria
65 home exercise program
246 community PR sites not involved in the study
94 declined to participate
155 consented
155 completed pre-PR assessment
1 withdrawn due to nickel allergy
2 withdrew from PR due to illness
152 randomized
76 assigned to pedometer and PR
76 assigned to PR
12 did not complete PR:
8 unwell
2 converted to a home exercise program
1 returned to work
1 unknown
1 withdrawn due to mental health issues
17 did not complete PR:
10 unwell
4 family commitments
1 converted to a home exercise program
1 alcohol problems
1 unknown
63 completed post-PR assessment
46 with complete pre- and post-PR primary outcome data
59 completed post-PR assessment
46 with complete pre- and post-PR primary outcome data
20 did not attend 6 month assessment:
12 unable to contact
3 unwell
1 family commitments
1 too much hassle
1 unknown
2 deaths
19 did not attend 6 month assessment:
13 unable to contact
3 unwell
1 unknown
2 deaths
56 completed the 6 month assessment
44 with complete pre- and 6 months post-PR primary outcome data
57 completed the 6 month assessment
49 with complete pre- and 6 months post-PR primary outcome data

FIGURE 1: CONSORT diagram

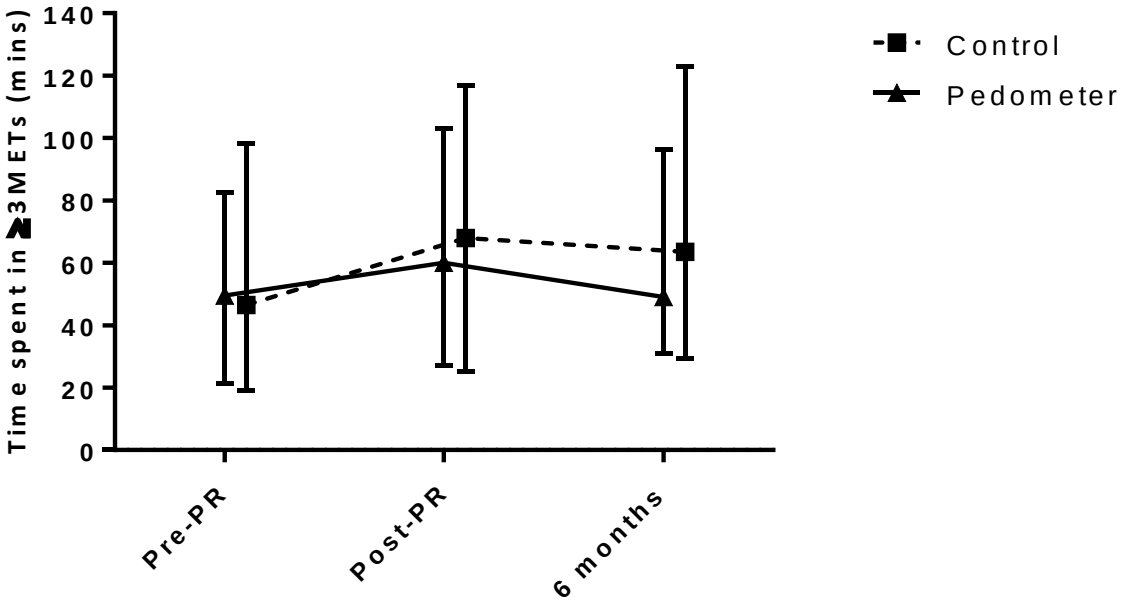

FIGURE 2: Daily time spent ≥3 METs before, after and 6 months following PR in the control and intervention group

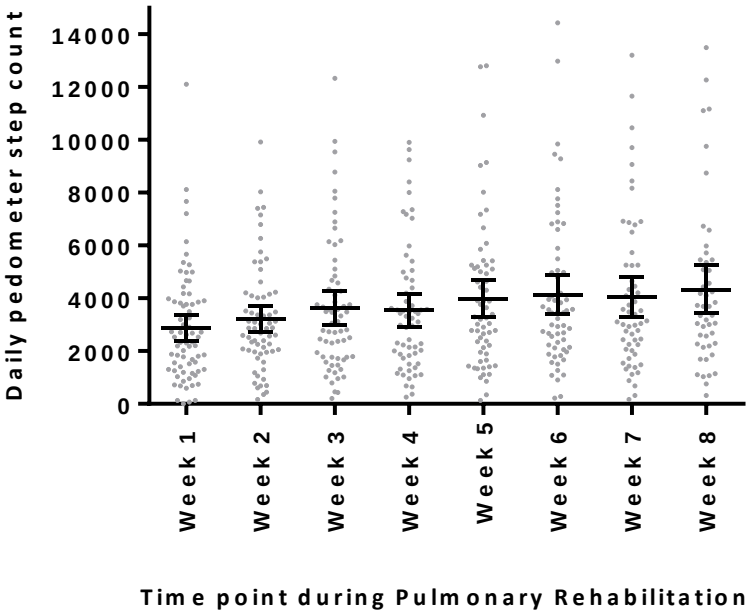

FIGURE 3: Progression of daily pedometer step count targets during pulmonary rehabilitation among participants allocated to the intervention group. Horizontal lines show median (Q1, Q3) values

ONLINE SUPPLEMENT

Pedometer step count targets during pulmonary rehabilitation in COPD: a randomized controlled trial

Pulmonary Rehabilitation program

Pulmonary rehabilitation (PR) was an 8-week outpatient exercise and multidisciplinary education program. It was delivered according to the British Thoracic Society Quality Standards for PR (1) and comprised two supervised sessions of exercise and education, and at least one additional home-based exercise session per week. Each supervised session would last two hours (15 minutes warm up, 60 minutes supervised exercise, 45 minutes education). Respiratory physiotherapists supervised the exercise sessions which involved progressive, individually tailored aerobic and resistance training. Initial walking speed was prescribed at 80% of predicted peak oxygen consumption based on the Incremental Shuttle Walk test (ISW) performance (2) with the aim of patients exercising for 15 minutes continuously. Initial endurance cycling was set at a workload to achieve level 3 to 4 on the Borg Dyspnea Scale (3) with the aim of patients completing 15 minutes of continuous training. Lower limb resistance training was based on the American College of Sport's Medicine resistance training guidelines (4) with an initial prescription of 2 sets of 10 seated leg press repetitions based on 60% of a one-repetition maximum, as well as sit-to-stand, knee extension, hip flexion and hip abduction exercises with appropriate free weights and ankle weights. Upper limb resistance training comprised biceps curls, shoulder press and upright row with free weights. Patients received an individualised, written home exercise program during PR and an individualised structured, written plan for on-going exercise maintenance on completion of PR.

A multidisciplinary team, including physiotherapists, psychologists, dieticians, nurses, doctors, occupational therapists, dieticians, social workers, speech and language therapists

and expert patients, delivered the education sessions. They aimed to develop patients' understanding and holistic management of their disease, and topics included physical activity and exercise, medication use, diet, smoking cessation, coping strategies, as well as managing infections through early recognition, rescue medication and appropriate general practice/hospital presentation. Patients received a booklet of the topics covered in these sessions.

Further details on the intervention protocol

The additional intervention was the provision of a pedometer (Yamax Digiwalker CW700®, Yamax, Nottingham, UK), an individualised daily step count target, and a step count diary provided during and for 6 months following PR. The first step count target was to increase the pedometer step count from the baseline pre-PR assessment by 5% over the forthcoming week (e.g. 250 additional steps from a baseline mean daily step count of 5,000). Participants were encouraged to achieve the prescribed target each day and to record the attained pedometer step count in their step count diary each evening. The step count diary was a booklet listing the days of the week with a space beside each day for the participant to record the daily pedometer step count. Each week before their PR session, participants were reviewed by the trial coordinator, who was not involved in the PR program delivery, to prescribe a new daily step count target for the following week. The target was to achieve a 5% increase in the preceding week's average daily pedometer step count, as retrieved from the pedometer memory function. If the participant did not attend PR in person, the target was prescribed by telephone. At this weekly review, each patient was counselled on the importance of achieving the pedometer step count and was given advice on how to increase physical activity levels. The clinical team delivering the PR program were blinded to participants' group allocation.

On completion of the PR program, participants in the intervention group received a final step count target and a 6 month step count diary. This target was a 20% increase in step count from the baseline assessment. Participants were encouraged to achieve the prescribed target each day until the 6 month PR assessment and to record the attained pedometer step count in their step count diary each evening. Participants were encouraged to achieve this target until the 6 month PR assessment.

Physical activity measurement

Participants wore an accelerometer (SenseWear®, Body Media Inc, Pittsburgh, USA) and pedometer for 7 days following the baseline, post-rehabilitation, and, 6 month follow-up assessment visits. The accelerometer provides a valid, reliable, and, objective measure of physical activity in COPD (5). It is internationally recommended for use within intervention trials and data covering ≥22.5/24 hours for ≥5 days is advocated (6, 7). Mean daily step count and time spent performing moderate intensity physical activity (≥3 METs) was recorded (6-8). The mean daily pedometer step count over 7 days was also recorded. The Yamax pedometer was chosen as it has been used in previous experimental and observational studies involving COPD subjects and has been identified as the most reliable and valid pedometer currently available (9-14). Numerous studies have reported that it displays face and construct validity as well as inter-model reliability on flat ground at speeds above 2.5-3mph in healthy adults and COPD subjects (9, 11, 13, 15-17). However, the convergent validity is disputed due to inconsistent correlation with accelerometer-measured step count (16, 18)rec

RESULTS

TABLE 1: Reasons for missing accelerometer data

Time-point	Intervention group	Control group
Pre-PR to post-PR	**46 / 76 matched pairs**	**46 / 76 matched pairs**
	30 missing pairs: • **12 did not complete PR** • **14 provided insufficient accelerometer data** • **2 declined to wear the accelerometer** • **1 withdrawn from the study** • **1 allergic reaction to the acclerometer**	**30 missing pairs:** • **17 did not complete PR** • **12 provided insufficient accelerometer data** • **1 allergic reaction to the acclerometer**
Pre-PR to 6 month post-PR	**44 / 76 matched pairs**	**49 /76 matched pairs**
	32 missing pairs: • **20 did not attend the 6 months post-PR assessment** • **8 provided insufficient accelerometer data** • **3 declined to wear the accelerometer** • **1 allergic reaction to the acclerometer**	**27 missing pairs:** • **19 did not attend the 6 month post-PR assessment** • **6 insufficient accelerometer data** • **2 allergic reaction to the acclerometer**

TABLE 2: Baseline characteristics, change post-PR and change 6 months post-PR using complete cases

	Baseline characteristics			Change baseline to immediately post-PR			Change baseline to 6 months post-PR		
	Total (n=134)	Pedometer (n=64)	Control (n=70)	Pedometer (n=46)	Control (n=46)	p value	Pedometer (n=44)	Control (n=49)	p value
Primary outcome: Time ≥3 METs (minutes/day)	46 (19, 85)	45 (20, 81)	47 (18, 103)	8 (-2, 36)	12 (-4, 36)	0.71	2 (-29, 30)	6 (-16, 33)	0.70
Secondary outcome: Accelerometer step count (steps/day)	3323 (1654, 5535)	3293 (1717, 5502)	3456 (1567, 5925)	386 (-580, 787)	57 (-658, 855)	0.76	-308 (-1009, 269)	-571 (-1848, 187)	0.41
	n=151	n=76	n=75	n=58	n=55		n=47	n=51	
Pedometer step count (steps/day)	2418 (1440, 4261)	2329 (1416, 4449)	2531 (1440, 4062)	534 (53, 2152)	179 (-539, 1189)	0.06	350 (-630, 1434)	-296 (-722, 791)	0.12

Data are median (Q1, Q3). METs: Metabolic Equivalents; ISWT: Incremental Shuttle Walk Test.

TABLE 3: Results of ANCOVA analysis adjusting for baseline CRQ values

CRQ	p value
Dyspnea	0.13
Fatigue	0.01
Emotion	0.40
Mastery	0.24
Total	0.04

TABLE 4. Baseline characteristics and change in primary and secondary outcome measures in pedometer and control groups restricted to participants achieving ≥150 minutes of moderate intensity physical activity per week at baseline

Variable	Baseline (n=114)					
	Pedometer (n=57)	**Control (n=57)**				
Sex (male) (number (%))	**42 (74)**	**40 (70)**				
Age (years)	**68 (10)**	**68 (8)**				
FEV_1 (% predicted)	**51.1 (21.0)**	**51.4 (21.3)**				
FEV_1/FVC	**0.50 (0.14)**	**0.51 (0.15)**				
MRC score	**3 (1)**	**3 (1)**				
BMI (kg/m^2)	**27.4 (5.7)**	**27.1 (5.0)**				
	Change baseline to immediately following PR (n=114)			**Change baseline to 6 months following PR (n=114)**		
	Pedometer (n=57)	**Control (n=57)**	**p value**	**Pedometer (n=38)**	**Control (n=38)**	**p value**
Primary outcome: Time ≥3 METs (minutes/day)	10 (-2, 33)	10 (-3, 34)	0.85	2 (34, 27)	12 (-16, 30)	0.45
Secondary outcomes: Accelerometer step count (steps/day)	452 (64 to 967)	167 (290 to 623)	0.84	-319 (-989, 108)	-422 (-1304, -53)	0.85
Pedometer step count (steps/day)	1093 (70, 2360)	52 (-768, 1237)	0.05	350 (-630, 1987)	-458 (-1509, 679)	0.13
ISWT distance (meters)	69 (53 to 85)	73 (51 to 84)	0.33	39 (12 to 65)	36 (9, 63)	0.87
CRQ						
Dyspnea	3.6 (1.9 to 5.4)	5.5 (3.8 to 7.2)	0.13	2.1 (-0.1 to 4.3)	3.6 (1.7 to 5.4)	0.30
Fatigue	2.3 (1.3 to 3.4)	4.6 (3.2 to 3.0)	0.01	0.9 (-0.4 to 2.2)	2.1 (0.6 to 3.7)	0.24
Emotion	3.0 (1.7 to 4.3)	5.8 (3.4 to 8.3)	0.04	0.5 (-1.5 to 2.4)	3.2 (0.7 to 5.7)	0.9
Mastery	1.6 (0.6 to 2.5)	3.6 (2.1 to 5.1)	0.03	-0.5 (-1.9 to 0.9)	-0.4 (-1.8 to 1.0)	0.13
Total	10.5 (7.1 to 14.0	19.5 (13.6 to 25.5)	0.01	-5.7 (-10.5 to -1.0)	-6.4 (-10.3 to -2.5)	0.08

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